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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,577

05/26/2005

Andreas Bergmann

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2150

23405

7590

04/16/2008

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EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,577	<b>Applicant(s)</b> BERGMANN ET AL.	
	<b>Examiner</b> SHARON WEN	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment, filed 01/28/2008, has been entered  
Claims 1-12 have been canceled.  
Claims 14-17 have been added.  
Claims 13-17 are pending and currently under examination as they read on a method of for the detecting thyroid stimulating hormone (TSH) receptor autoantibodies in a biological sample.

2. Text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Action will be in response to Applicant's Arguments/Remarks, filed 01/28/2008.

The rejections of record can be found in the previous Office Action.

### ***Priority***

3. In view of Applicant's amendment, filed 01/28/2008, the domestic priority date for claims 13-17 is deemed the effective filing date of PCT/EP03/12129, i.e., 10/31/2003.

Applicant's claim for foreign priority is acknowledge. However, there does not appear to be a certified translation of the priority document, 10255144.8. Therefore, Examiner cannot determine whether the priority document provides sufficient written support for claims currently under examination, i.e., claims 13-17.

### ***Claim Objections***

4. The previous claim objection has been withdrawn in view of Applicant's amendment, filed 01/28/2008.

***Claim Rejections - 35 USC § 112 second paragraph***

5. The previous claim rejection under 35 USC § 112 second paragraph has been withdrawn in view of Applicant's amendment, filed 01/28/2008.

***Claim Rejections - 35 USC § 102***

6. The previous claim rejection under 35 U.S.C. 102(b) as being anticipated by Morgenthaler et al. (reference of record) has been withdrawn in view of Applicant's amendment, filed 01/28/2008.

7. Claim 13 and newly added claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Parmentier et al. (U.S. Patent 6,228,597 B1, see entire document) as evidenced by Weir et al. (*Handbook of Experimental Immunology in Four Volumes*, Volume 1: Immunochemistry, Forth Edition, 1986, Blackwell Scientific Publications, Palo Alto, CA, USA, pages 34.7-34.8).

Given the absence of a rebuttal to the outstanding rejection of record, it appears that Applicant has acquiesced to the rejection of record.

It is noted that the amended claim 13 and newly added claims 14-15 recite product-by-process limitation in the recitation of "affinity-purified polyclonal human autoantibodies against TSH receptor" wherein the antibody is "obtained by purification by affinity chromatography from a pool of sera of Graves' disease patients". However such process does not distinguish from the antibody in the art. In particular, Parmentier teaches the antibody used in the method to detect TSH receptor is purified polyclonal autoantibody against TSH receptor from serum of patients with Graves's disease (see column 8, lines 60-68 and column 14, lines 51-68). Even though Parmentier does not teach that the antibody is obtained by affinity purification, *per se*, given the prior art teaches the same or nearly the same purified anti-TSH receptor autoantibody, under the broadest reasonable interpretation, the same antibody can also be obtained by affinity chromatography. Therefore, Parmentier anticipates the present claims.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In addition, Parmentier teaches the antibody to be labeled with a radioactive isotope (see column 10 lines 6-25) which reads on direct labeling of the antibody as recited in claims 16-17.

Taken together, Parmentier anticipates the present claims.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Claim Rejections - 35 USC § 103***

8. Claim 13 and newly added claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parmentier et al. (U.S. Patent 6,228,597 B1) in view of Brown et al. (*J. of Clinical Endocrinology and Metabolism*, 1983, 56:156-163, cited in IDS).

Given the absence of a rebuttal to the outstanding rejection of record, it appears that Applicant has acquiesced to the rejection of record. Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Double Patenting***

9. Claim 13 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,228,597. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons stated in the previous Office Action, mailed 09/17/2007.

Given the absence of a rebuttal to the outstanding rejection of record, it appears that Applicant has acquiesced to the rejection of record. Therefore the rejection stands for the reasons of record.

### ***Conclusion***

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./

Examiner, Art Unit 1644

April 8, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644